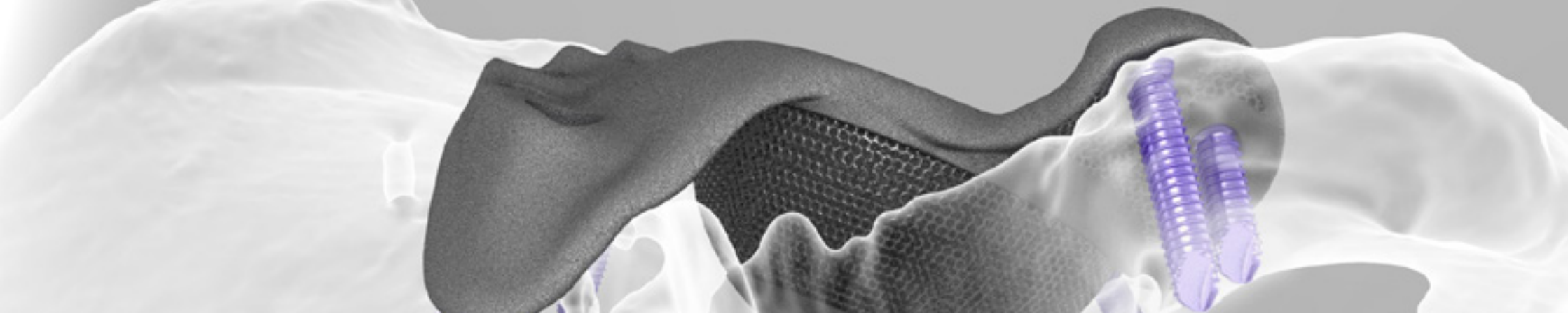


OSSIS

A custom solution fit for you and your patient

AceOS™ CUSTOM ACETABULAR IMPLANT



Who are Ossis?

Ossis deliver custom orthopaedic solutions for complex orthopaedic cases

A world leader in customised, clinically directed, implant solutions.

Over the last 15 years Ossis' orthopaedic surgeons and biomedical engineers have been at the leading-edge of innovation in custom implants.

Already, Ossis has helped scores of patients who have had their lives successfully and significantly enhanced by Ossis' custom implants. Patients regain their mobility and independent lifestyle by replacing their severely damaged joints with advanced and proven custom orthopaedic solutions.

Ossis meet the highest standards of quality and service and are committed to their ISO 13485 quality accreditation.

Ossis' custom implants embody the results of its extensive investment in innovation and technology.

Ossis combines the use of imaging and design technologies and powerful communication software platforms with its extensive implant design and clinical experience to create the most advanced and effective custom implants available for a broad range of major anatomical defects.

Technologies include:

- Additive Manufacturing technologies
- Proprietary surface textures
- Proprietary porous scaffolds
- Initial fixation through locking head screw technology

The Ossis team: Focused on successful patient outcomes

Ossis are a team of orthopaedic surgeons, biomedical engineers and support staff who all work closely with the prescribing orthopaedic surgeon. The team value their open communication style to ensure success in customising the surgeon's needs. Together, the team strive to deliver the best solution for the surgeon, to ensure successful patient outcomes.

Our objective: *To have all surgeons completing surgery, confident that working with Ossis is easy, that surgeries are quick, stress-free and that the Ossis custom implants are exceptionally effective.*

Our mission: *To continue to evolve our technology, to make more impossibles possible; to achieve the best patient outcomes in all areas of joint reconstruction.*

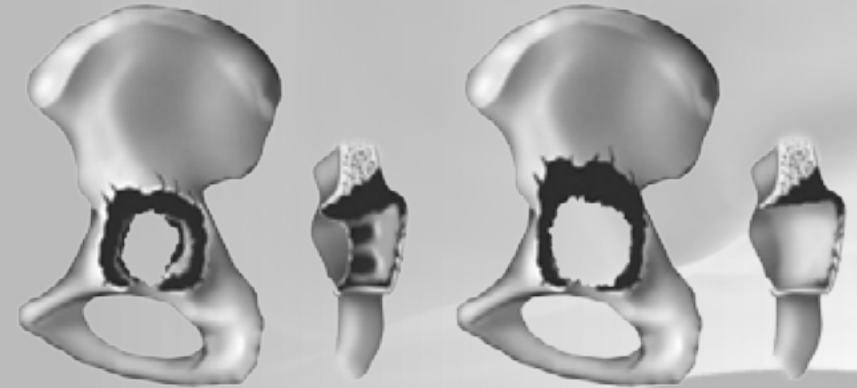
AceOS™

Custom Acetabular Implant

Ace surgery. Enable your patient to Ace life again

Severe pelvic bone loss or pelvic dissociation are best treated using an implant that has been specifically designed to match the patient's anatomy.

The AceOS™ Implant is designed to treat Paprosky 3a, 3b and dissociation defects, as demonstrated by the images below.



Patients facing these defects are suffering from severe degradation of their joints and have limited options. Left untreated, these patients face a life of pain, struggling with everyday tasks.

The AceOS™ Implant has been used to treat the following pathologies:

- Discontinuity
- Paprosky 3b
- Paprosky 3a
- DDH
- Infection
- Trauma





Ossis creates a custom solution fit for only you and your patient.

Designed and manufactured to the highest standards

Integrating advanced image processing, design software and manufacturing technologies to deliver an innovative solution for otherwise very complex surgical procedures.

Add an Ossis Biomedical Engineer to your surgical team

An interactive and open communication approach is maintained with the surgeon during the design phase to ensure the final solution is customised to the surgeon's needs.

Shorter lead time

Advanced design and manufacturing technologies contribute to a lead time of only three to four weeks after receiving the CT scan.

Striving for a successful surgery

By performing much of the surgical planning before getting into theatre, the unknowns are removed before surgery.

Preoperative models supplied with every surgery

Ossis provides sterilisable plastic anatomical models and a sterilisable plastic trial of the implant. These models allow the surgeon to undertake preoperative surgical planning and being sterilisable they can be used for intraoperative reference. This leads to shorter successful surgeries and a successful patient outcome.



Enhance osseointegration with the patient's host bone

The AceOS™ Implant is manufactured using advanced additive manufacturing techniques which create a solid one-piece component with proven¹ osseointegrative properties. Additive manufacturing allows for the custom shape with reduced lead time and the porous structure built as one piece with the solid.

[1] Osseointegration of EBM Titanium Scaffolds - Download from here: www.ossis.com/resources

Enter the design process with us

A process of collaboration

Ossis' engineers work with the surgeon to design the implant. Surgeon approval of the design is based on 3 dimensional images of the proposed implant, both in isolation and in position on the patient's anatomy, including screws positions and trajectories.

Funding application: Ossis can help

Ossis can support funding applications for both the public and private sectors across Australasia.

Design and ordering process

WEEK 1: **Information gathering**

- Log in to the Ossis website portal: <http://crm.ossis.com/login>
- Send Ossis your CT scans and completed prescription form
 - DICOM Grid User Guide for Surgeons (www.ossis.com/resources)
 - Custom Acetabulum Reconstruction Prescription (www.ossis.com/resources)
- Ossis will send you a quote with segmented images and design proposal

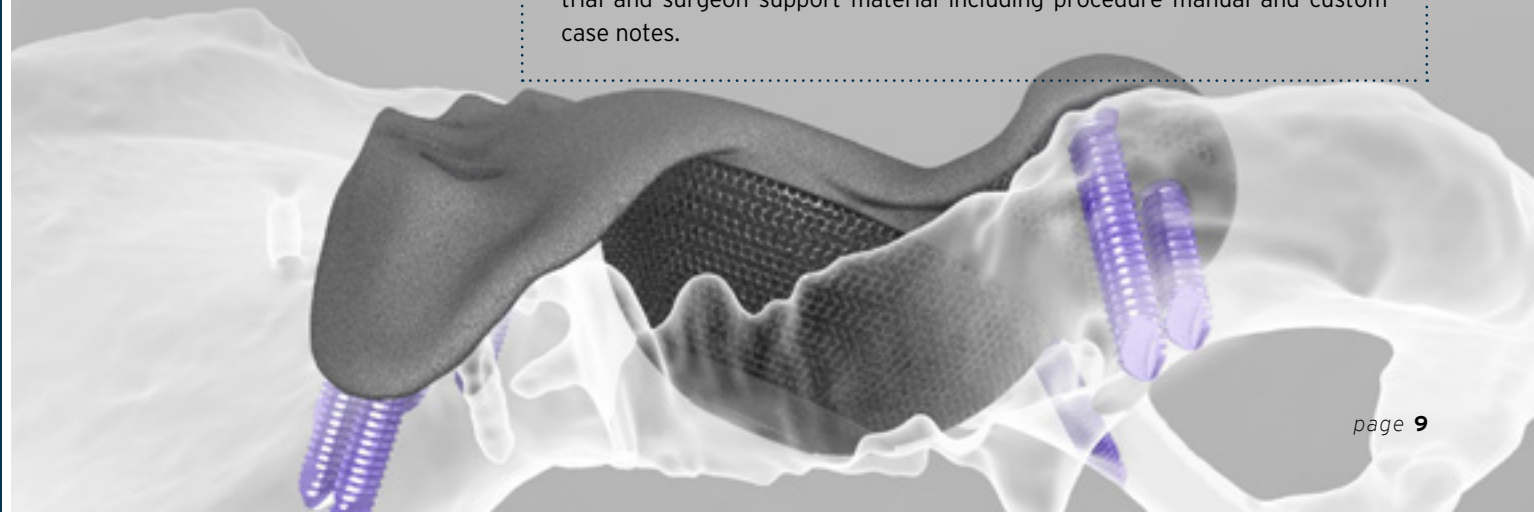
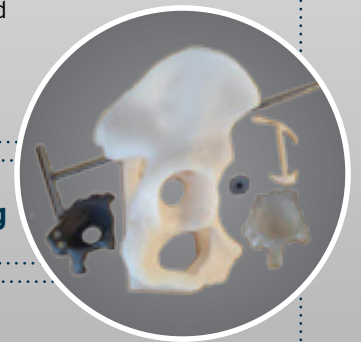
WEEK 2: **Design approval**

- Ossis will send you a Design Report with detailed design specification for your approval
- You approve the AceOS™ Design

WEEKS 3 & 4: **AceOS™ Manufacturing**

WEEK 4: **AceOS™ Implant delivery**

Ossis will send you the completed AceOS™ Implant with anatomical model and trial and surgeon support material including procedure manual and custom case notes.



Technology

Promoting Osseointegration

Material technology - Additive Manufacturing of Titanium Alloy

For every custom implant, Osis utilises additive manufacturing of Titanium alloy (Ti6Al4V) with the application of porous metal scaffolds on all appropriate bone facing surfaces. The implant surface is designed in direct contact with the host bone and utilises geometry that conforms to the patient's anatomy. This provides an optimal environment for osseointegration.

Patented highly porous scaffold structure

A patented scaffold structure for the highly porous additively manufactured metal is used in Osis implants. Scaffold parameters have been derived using standard trabecular bone nomenclature. Extensive research has been conducted to refine parameters to achieve desired topological characteristics within the porous metal niche.

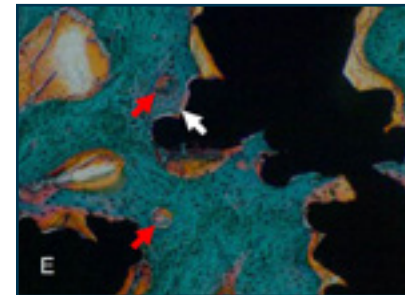
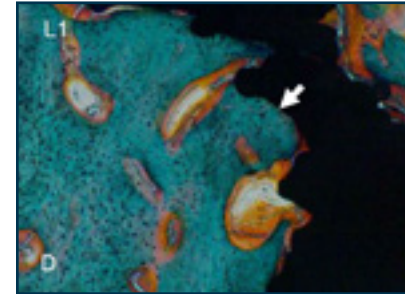
An interconnected network of pores provides an average porosity of 70%.

The porous structure enables the bone to grow into the pores of the construct so that strong biological fixation of the implant in the bone is achieved.

EBM porous scaffold at x50 magnification using scanning electron microscope (SEM).

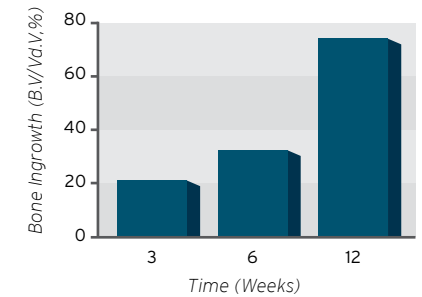


An in-vivo sheep model study² showed good bone apposition and titanium pore ingrowth. Maximum pull-out forces were tested at 3, 6 and 12 weeks respectively and provide the strength of the bone-implant interface.



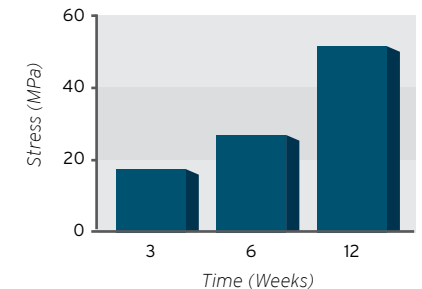
Bone remodelling at the periphery and centre of EBM samples implanted in the proximal tibia of sheep after 12 weeks in situ. Implants appear black as they do not transmit light. Direct bone to implant contact is identified in all samples by a white arrow. Evidence of bone remodelling and the formation of Haversian systems in the central zone is shown by red arrows.

Bone Ingrowth



Bone in growth (B.V/Vd.V,%) recorded during pull-out tests of cylindrical samples (diameter 8mm)

Interfacial Shear Stress



Interfacial shear stress in a cortical implantation scenario (mean + SE).

[2] Osseointegration of EBM Titanium Scaffolds - Download from here: www.osis.com/resources

Strong, stable fixation

Locking head screws, expertly positioned for your patient.

The AceOS™ Implant is designed to provide an optimal solution for patients with extensive acetabular bone loss. To achieve the strongest and most stable initial fixation, it is important to use locking head screws. Precise computer driven preoperative planning enables Ossis' Biomedical Engineers to achieve the best possible locking head screw trajectories and lengths. The use of locking head screws prevents compression of the bone and does not restrict blood supply to bone, enabling and enhancing osseointegration of the AceOS™ Implant.

Ossis' diverging locking head screw configuration increases the required bending moment for failure. The locking head screws provide greater initial stabilisation which substantially reduces micro-motion. The pull out strength of locking head screws is substantially higher than conventional cancellous screws as it is difficult for one screw to fail unless all adjacent screws fail.

Cost effectiveness

AceOS™ implants provide the best outcomes for surgeons, their patients and the healthcare system.

A cost saving of 13.3%

Studies into the use of the AceOS™ Implant show a total cost saving of approximately 13.3% over the use of existing modular systems. This cost saving stems from:

- Improved bed and theatre utilisation
- Reduced rehabilitation time
- Mitigation of re-revision risk.

Proven technology with clinical results

Ossis has provided custom acetabular solutions to scores of patients over New Zealand and Australia. These solutions have improved the surgeon and patient experience and led to the successful restoration of acetabular function which would otherwise be difficult to achieve with an off-the-shelf solution.

MEASURE	MEAN	RANGE
Oxford Score	48	34 - 60
Womac Score	96	67 - 120
Harris Score	81	36 - 100

Probability of Osseointegration	100%
<3mm Migration of Hip Centre	92%

Testimonials

"I have been using Osis for custom acetabular components for the last few years. These have been very helpful for very large complex defects in joint reconstruction for failed hip replacements but also for tumour reconstruction in the primary situation. They negate the use of complex modular components that are difficult in my experience to fit in these very major defects and give immediate stability and so far good survival."

Surgeon, Hamilton NZ

"The AceOS custom delivers operative efficiency and precision to my advance revision cases."

Surgeon, Sydney AU

"The surgery went very well. The suggested bone removal from the acetabulum was minimal and very accurate. The definitive implant fitted perfectly and the locking screw holes were in exactly the right place. The initial fixation and stability was excellent. The leg length discrepancy was reduced to a negligible amount.

The early postoperative outcome so far has been very positive with no complications and a very satisfied patient and surgeon. There is no doubt in my mind that this implant designed by Osis was the best option for this patient and this has significantly contributed to her excellent early outcome."

Surgeon, Tauranga NZ

LEGAL DISCLAIMER

Osis designs and manufactures patient-specific implants which are used by surgeons to treat patients with unique clinical needs that cannot be effectively treated with off-the-shelf products.

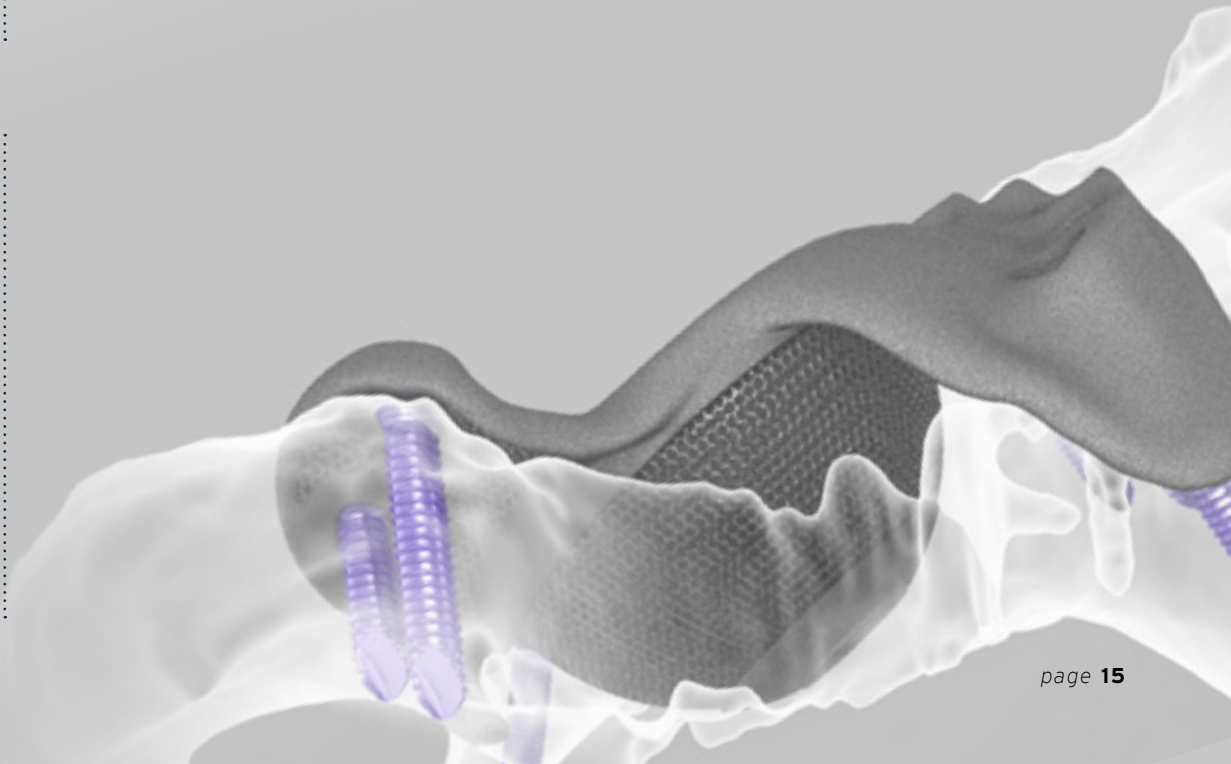
Osis implants are unique to the patient. Mechanical testing, engineering data and clinical test results are often unavailable for such custom devices and the mechanical integrity of each device cannot be validated. Surgeons should consider these issues and inform their patients about the additional risks associated with custom implants.

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